K012777

OCT 22 2001

Bayer Diagnostics

ASC:180 and ADVIA Centaur anti-Tg Immunoassays

Section 2: Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	Kenneth T. Edds Ph.D
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Date Summary Prepared:	July 17, 2001

2. Device Information

Proprietary Name:	ADVIA Centaur and ACS:180 anti-Tg Immunoassay
Common Name:	anti-Tg Immunoassay
Classification Name:	Thyroid autoantibody immunological test system
Class:	Class II
CFR:	21 CFR 866.5870
Product Code:	JZO

3. Predicate Device Information

Name:	DYNOTest® anti-Tg_n
Manufacturer:	BRAHMS Diagnostica, GmbH Neuendorfstrasse 25 D-16761 Hennigsdorf Germany
510(k) Number:	K992790

4. Device Description

The ACS:180 and ADVIA Centaur anti-Tg are a competitive chemiluminescence immunoassay intended for the quantitative determination of autoantibodies against thyroglobulin in human serum and plasma. A polyclonal human anti-Tg antibody bound to the solid phase competes with autoimmune anti-thyroglobulin antibodies in patient samples, standards, and controls for directly labeled native human thyroglobulin the lite reagent. Following incubation, unreacted labeled thyroglobulin and unreacted antibodies from the sample are washed from the reaction mixture. The chemiluminescence of the reacted, labeled thyroglobulin is measured in a luminometer. The measured chemiluminescence is inversely proportional to the quantity of anti-thyroglobulin antibody in the sample.

5. Statement of Intended Use

The ACS:180 and ADVIA Centaur anti-Tg Immunoassays are competitive, chemiluminescence immunoassay for the quantitative determination of autoantibodies against thyroglobulin (TG) in human serum and plasma for use on the automated analyzer marketed by Bayer Corporation. The ACS: 180 and ADVIA Centaur anti-Tg Immunoassays are used as an aid in the diagnosis of Hashimoto's and Graves' disease, autoimmune diseases affecting the thyroid gland.

6. Summary of Technological Characteristics

The ACS:180 and ADVIA Centaur anti-Tg Immunoassays are similar to the BRAHMS Diagnostica DYNOTest® anti-Tg kit (K992790) in the indications for use, format, solid phase, performance characteristics, and results. The ACS:180 and ADVIA Centaur anti-Tg tests differ from the predicate device in their intended use on an automated analyzer as compared to a manual coated tube technique. In the automated methods, a chemiluminogenic molecule (acridinium ester) is used to replace the ^{125}I signal used in the DYNOTest anti-Tg manual assay.

7. Method Comparison

The data represented in this document is organized into two components:

1. Comparison of the ACS:180 anti-Tg to the predicate device DYNOtest anti-Tg_n (K992790). Results in sections 3 & 4.
2. Comparison of the ADVIA Centaur to the ACS:180 used transference. Transference is a method recommended by NCCLS (C28-A, How to Define Reference Intervals in the Clinical Laboratory; Approved Guideline). This document discusses and provides guidelines for "transference of s reference interval for an analyte measured by a different analytical system, different method or different instrument. Results are in section 5.

Substantial equivalence to the DYNOTest kit, cleared under K992790, is based on clinical comparison using 581 serum samples from normal blood donors (n=293) and patients with Graves' disease (n=99), and Hashimoto's thyroiditis (n=189). Agreement of normal group based on a 2 X 2 agreement table was 286/293 = 97.6%.

ACS:180 vs. DYNOtest

Normal patients:

DYNOtest anti-Tg_n

		Positive	Negative
ACS:180 anti-Tg	Positive	23	7
	Negative	0	263

% Agreement = 97.6 (286/293)

Graves patients:

DYNOtest anti-Tg_n

		Positive	Negative
ACS:180 anti-Tg	Positive	28	11
	Negative	1	59

% Agreement = 87.9 (87/99)

Hashimoto's patients:

DYNOtest anti-Tg_n

		Positive	Negative
ACS:180 anti-Tg	Positive	78	55
	Negative	0	56

% Agreement = 70.9 (134/189)

This correlation study demonstrates that the ACS:180 anti-Tg assay is substantially equivalent to the legally marketed predicate device, the BRAHMS Diagnostica DYNOTest anti-Tg assay; 510(k) Number K992790, in the diagnosis of thyroid normals. The sensitivity (more diseased patients found positive) of the ACS:180 anti-Tg assay is greater the BRAHMS Diagnostica DYNOTest anti-Tg assay; 39.9% vs. 29.3% for Graves and 70.4% vs. 41.2% for Hashimoto, respectively.

ADVIA Centaur vs. ACS:180

For 255 serum samples in the range of 10 to 500 U/mL, the relationship between the ADVIA Centaur anti-Tg assay and the ACS:180 anti-Tg assay is described by the equation:

ADVIA Centaur anti-Tg = 1.03 (ACS:180 anti-Tg) + 2.29 U/mL
Correlation Coefficient (r) = 0.989

The diagnostic concordance between the two assays is shown in the following table:

ACS:180 anti-Tg

		Positive	Negative
ADVIA Centaur anti-Tg	Positive	110	4
	Negative	1	140

% Agreement = 98% (250/255)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 22 2001

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K012777
Trade/Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur anti-Tg Assay
Regulation Number: 21 CFR § 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: II
Product Code: JZO
Dated: August 15, 2001
Received: August 20, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012777

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur anti-Tg Assay

Indications for Use:

The ACS:180 and ADVIA Centaur anti-Tg Immunoassays are competitive, chemiluminescence immunoassay for the quantitative determination of autoantibodies against thyroglobulin (TG) in human serum and plasma for use on the automated analyzer marketed by Bayer Corporation. The ACS:180 and ADVIA Centaur anti-Tg Immunoassays are used as an aid in the diagnosis of Hashimoto's and Graves' disease, autoimmune diseases affecting the thyroid gland.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Sonsan S. Altail
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012777